DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	3/3/2016-4/15/2016* FEI NUMBER 3012223534

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Svetislav Milic, R.Ph. , Owner

FIRM NAME	STREET ADDRESS
Colonia Care Pharmacy	515 Inman Ave Ste A
CITY, STATE, ZIP CODE, COUNTRY Colonia, NJ 07067-1114	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is insufficient test data supporting the labeled Beyond Use Date (BUD) provided for some injectable products or in-process (b) (4) (b) (4) used to prepare them. For example:

- Papaverine/Phentolamine/Prostaglandin-E1 Injection Solution ("Trimix"), lot 020216A, was prepared and filled on 2/2/16 in a multi-use vial, with a BUD of 30 days refrigerated, and 6 months when frozen. The finished product was not tested for sterility, and was made using (b) (4) prepared from non-sterile starting materials, one of which was expired (Papaverine (b) (4) expired approx. 23 days earlier, on 1/10/2016).

  Each (b) (4) was prepared in a (b) (4) and stored in (b) (4) area (Papaverine (b) (4) produced on (b) (4) Phentolamine (b) (4) produced on (b) (4) ; and Alprostadil (b) (4) produced on (b) (4)

  No data was provided demonstrating these (b) (4) or finished sterile drug product have been evaluated for potency, purity, sterility, or endotoxin levels at the end of their labeled BUDs. The (b) (4) may contain preservatives, but their effectiveness over the labeled BUDs in (b) (4) has also not been assessed.

- Methylcobalamin and Acetylcysteine Injection Solution, lot 120715M, was prepared and filled on 12/07/15 in pre-filled syringes, with a BUD of 30 days refrigerated, and 6 months when

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frozen. The finished product was not tested for sterility, and was made from an i (b) (4) with BUD (b) (4) (prepared (b) (4), which is stored in (b) (4) area. No data was provided demonstrating the (b) (4) or finished sterile drug product have been evaluated for potency, purity, sterility, or endotoxin levels at the end of their labeled BUDs, or that the container-closure system (syringes) used for the finished drug product is suitable for its intended use.

- Dexamethasone 24mg/ml Injectable, lot 031716N, was aseptically filled on 3/17/2016, with instructions to provide a BUD of "45 days after compounding date" but was labeled "06/01/16 Frozen", instead of the specified "5/1/2016" in the record. There was no sterility, potency, purity, or endotoxin testing performed to support the labeled BUD.

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, not all finished sterile drug products are tested for sterility and endotoxin levels, where appropriate, and there is no testing schedule. For example:

- Papaverine/Phentolamine/Prostaglandin-EI Injection Solution ("Trimix"), lot 020216A, was prepared and filled on 2/2/16, and given a BUD of 30 days refrigerated, and 6 months when frozen. There was no testing of sterility or endotoxin levels of the finished drug product.

- Methylcobalamin and Acetylcysteine Injection Solution, lot 120715M, was prepared and filled on 12/07/15, and given a BUD of 30 days refrigerated, and 6 months when frozen. There was no testing of sterility or endotoxin levels of the finished drug product.

- Atropine Ophthalmic Solution, lot 020316J, was prepared and filled on 02/03/16, and given a BUD of 3 months. There was no testing of sterility of the finished drug product.

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- Hydrogen Peroxide Injectable, lot 010516G, was prepared and filled on 01/05/16, and given a BUD of 1 month. There was no testing of sterility or endotoxin levels of the finished drug product.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, in the laminar flow (b) (4) which is located in an unclassified room and is used for aseptic filling of sterile drug products, the evaluation of unidirectional airflow continuity (e.g., smoke studies), airborne viable and non-viable particle counts, and surface monitoring for microbiological contamination are not performed under dynamic conditions that represent routine usage.

The air and surface monitoring are performed (b) (4) (b) (4) (b) (4) when it is not being used, and not routinely during aseptic filling, which may occur (b) (4) (b) (4). In addition, personnel monitoring consists of gloved fingertip monitoring ((b) (4)) every (b) (4), and is performed as an independent operation, not after completion of aseptic filling, to represent routine conditions.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, (b) (4) media fill testing is performed to support aseptic filling practices, in which (b) (4) (b) (4). This does not represent the most challenging conditions, in that up to (b) (4) may be filled at one time. For example, Dexamethasone 24mg/ml Injectable, lot 031716N, was prepared on 3/17/16, and filled into (b) (4).

OBSERVATION 5

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

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Specifically, the filling record for Papaverine/Phentolamine/Prostaglandin-E1 Injection Solution, lot 020216A, executed 2/2/16, notes "Protect from light", but the finished drug product is prepared in "30ml Clear Sterile vial". There is no assurance the drug is adequately protected from light.

***DATES OF INSPECTION**

3/03/2016(Thu),3/07/2016(Mon),3/21/2016(Mon),4/04/2016(Mon),4/06/2016(Wed),4/08/2016(Fri),4/15/2016(Fri)

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